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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,615

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Myung-Hwa Kim

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EXAMINER

SZNAIDMAN, MARCOS L

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

05/29/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/562,615	Applicant(s) KIM ET AL.	
	Examiner MARCOS SZNAIDMAN	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/24/09.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3 and 5-11 is/are pending in the application.
- 4a) Of the above claim(s) 1 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3 (in part) is/are allowed.
- 6) ☒ Claim(s) 5-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2 pages / 01/20/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

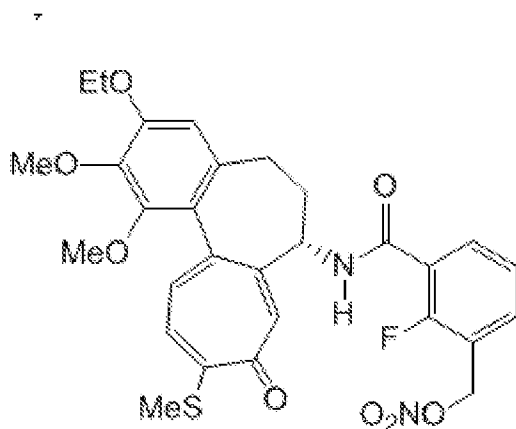
This office action is in response to applicant's reply filed on November 24, 2008.

Status of Claims

Amendment of claims 1, 3, 5 and 6; cancellation of claim 2, and addition of claims 7-11 is acknowledged.

Claims 1, 3, 5-11 are currently pending and are the subject of this office action.

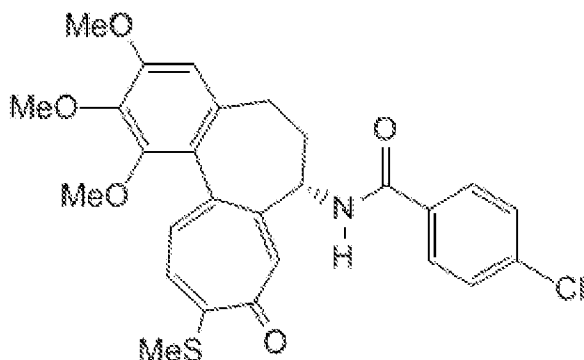
In the reply filed on June 3, 2008, Applicant elected the compound N-[7S-3-ethoxy-1,2-dimethoxy-10-methylsulfonyl-9-oxo-5,6,7,9-tetrahydro-benzo[a]heptalen-7-yl]-2-fluoro-3-nitrooxymethyl-benzamide as the elected species, corresponding to the following structure:



which is encompassed by the following claims: 3, and 5-11. Due to the amendment of Claim 1 by Applicant, Claim 1 no longer encompasses this structure.

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Since the above elected species was found free of prior art, in the Office Action mailed on August 27, 2008, the examination was expanded to the following species: 4-chloro-N-[5,6,7,9-tetrahydro-1,2,3-trimethoxy-10-(methylthio)-9-oxobenzo[a]heptalen-7-yl]-benzamide (CAS # 147950-73-0), which corresponds to the following structure:



which is encompassed by the following claims: 3, and 5-11.

Both species are currently under examination, as a consequence the following claims: 3 and 5-11, encompass either one or both species. Claim 1 is withdrawn since, after Applicant's amendment it no longer reads on any of the two examined species.

Claims 3 and 5-11 are presently under examination.

Priority

The present application is a 371 of PCT/KR04/01518 filed on 06/23/2004, and claims priority to foreign Application: REPUBLIC OF KOREA 10-2003-00415467 filed on 06/25/2003.

Information Disclosure Statement

The Information Disclosure Statement filed on January 20, 2009 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. A signed copy of the IDS is attached hereto.

Rejections and/or Objections and Response to Arguments

Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated (Maintained Rejections and/or Objections) or newly applied (New Rejections and/or Objections, Necessitated by Amendment or New Rejections and/or Objections not Necessitated by Amendment). They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 5-6 and 8-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5-6 and 8-11 depend (in part) from claim 1 which is withdrawn, as such they are incomplete. Correction is required.

Claim Rejections - 35 USC § 103 (New Rejection Necessitated by Amendment)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

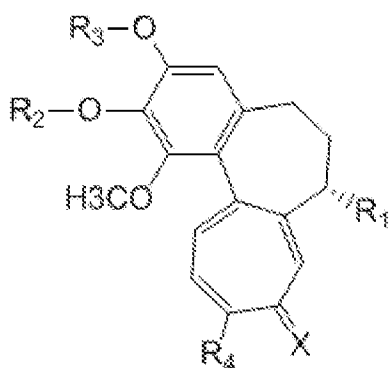
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guan et. al. (J. Med. Chem. (1988) 41:1956-1961, cited in prior Office Action).

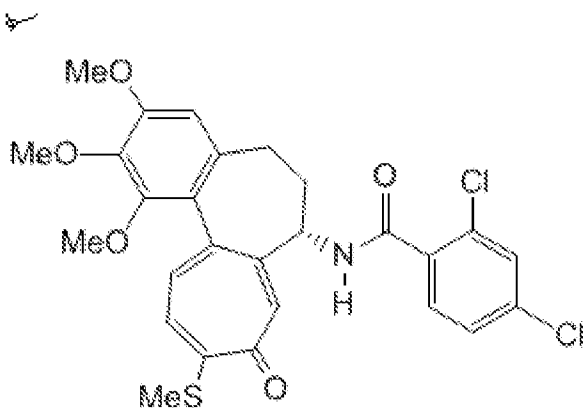
Claims 7-11 recite a tricyclic derivative represented by the following Formula I or pharmaceutically acceptable salts thereof:



Formula I

which based on the limitations of claim 7, encompasses the following compound:

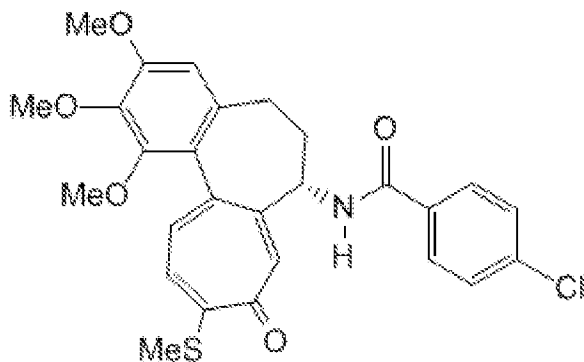
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from now on: Compound A, in

which R1 is T1-B1, and wherein T1 is -HNCO- , and B1 is group (a), wherein R6 = R7 = Cl, and $n_2 = n_3 = 0$ (see claim 7).

For claims 7-11, Guan et. al. teach the following compound: 4-chloro-N-[5,6,7,9-tetrahydro-1,2,3-trimethoxy-10-(methylthio)-9-oxobenzo[a]heptalen-7-yl]-benzamide (CAS # 147950-73-0) (see compound 21 on scheme 1 on page 1958), which corresponds to the following structure:



from now on Compound B.

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Guan does not teach any of the compounds encompassed by Formula I above, including Compound A. However, Compound A of the instant application and compound B of the prior art, differ only in that compound A has two chlorine atoms in the aromatic ring, while compound B has only one. In other words: these two compounds are identical, except for the presence of a Chlorine atom in compound A, instead of a Hydrogen atom in compound B. MPEP 2144.09 section II, says that homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by $-CH_2-$ groups) are generally of sufficient close structural similarity that there is presumed expectation that such compounds possess similar properties. MPEP 2144, Section III states: prior art structures do not have to be true homologs or isomers to render structurally similar compounds *prima facie* obvious. *In re Payne*, 606 F.2d 303, 203 USPQ 245 (CCPA 1979) (Claimed and prior art compounds were both directed to heterocyclic carbamoyloximino compounds having pesticidal activity. The only structural difference between the claimed and prior art was that the ring structures of the claimed compounds had two carbon atoms between two sulfur atoms, whereas the prior art ring structures had either one or three carbon atoms between two sulfur atoms. The court held that although the prior art compounds were not true homologs or isomers of the claimed compounds, the similarity between the chemical structures and properties is sufficiently close that one of ordinary skill in the art would have been motivated to make the claimed compounds in searching for new pesticides). *In re Gyurik*, 201 USPQ 552, 596 F2d 1012 on page 557 states: "In obviousness rejections based on close similarity in chemical structure, the necessary motivation to make a claimed compound, and thus the *prima facie* case of obviousness,

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risks from the expectation that compounds similar in structure will have similar properties.” In this case, it is expected that compounds A and B, differing by only one Chlorine atom, would have similar chemical, physical and biochemical properties.

At the time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to replace an Hydrogen atom of the compound described in the prior art (Compound B) with a Chlorine atom (Compound A), with the motivation of obtaining compounds with similar chemical, physical and biological properties, thus resulting in the practice of claims 7-11, with a reasonable expectation of success.

Claims 5 and 6 further limit claim 7 wherein the compounds of claim 7 are part of a composition further comprising a pharmaceutically acceptable excipient.

For claims 5 and 6, Guan further teaches that the compounds of the invention, including compound B, are pharmacologically active (Topoisomerase II inhibitors, see title for example) and were tested in an *in vitro* assay (see Table I on page 1957) in dilute water (a pharmaceutically acceptable excipient) solutions.

The statements in claims 5 and 6: “an anticancer agent”, “anti-proliferation agent” or “an angiogenesis inhibitor” are considered intended uses and do not add any new limitation to the claim. *Catalina Mktg. Int’l, Inc. V. Coolsavings.com, Inc.*, 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (fed. Cir. 2002). “The recitation of a new intended use for an old product does not make a claim to that old product patentable.” *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997).

At time of the invention, it would have been *prima facie* obvious for a person of ordinary skill in the art to further add a water or any other pharmaceutically acceptable

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excipient to compound B, with the motivation of better administering compound B to a patient, since Guan teaches that compound B and its analogues are pharmacologically active compounds, thus resulting in the practice of claims 5 and 6, with a reasonable expectation of success.

Allowable Subject Matter

Claim 3 is allowable in part, but only insofar as it relates to the applicant elected species which has been found to be free of prior art.

Claim 3 is withdrawn in part, however, with regard to the non-elected subject matter contained therein.

Accordingly, claim 3 would be allowable at this time if amended to remove the non-elected subject matter.

Withdrawn Rejections and/or Objections

Claims rejected under 35 USC 112, second paragraph.

Due to applicant's amendment of claims 5 and 6 the written description rejection is now moot.

Rejection under 35 USC 112, second paragraph is withdrawn.

Claims rejected under 35 USC 102 (b)

Due to Applicant's amendment of claims 5 and 6, cancellation of claim 2 and withdrawal of claim 1, the 102 rejection is now moot.

Rejection under 35 USC 102(b) is withdrawn.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCOS SZNAIDMAN whose telephone number is (571)270-3498. The examiner can normally be reached on Monday through Thursday 8 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571 272-0580. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MARCOS SZNAIDMAN/
Examiner, Art Unit 1612
May 20, 2009

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612